JUL 12 2005

~~CONFIDENTIAL~~

510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR § 807.92.

Submitter Information:

SeaSpine, Inc.
Contact: Diana Smith
2302 La Mirada Drive
Vista, CA 92081-7862
Phone: 760-727-8399 Fax: 760-727-8809

Company Registration Number: 2032593

Submission Correspondent:

SeaSpine, Inc.
Contact: Diana Smith, Manager of
Regulatory Affairs and Quality Assurance
2302 La Mirada Drive
Vista, CA 92081-7862
Phone: 760-727-8399 Fax: 760-727-8809

Date Summary Prepared: June 15, 2005

Classification Name:

Pedicle Screw Spinal System
MNH (Class II) - 888.3070(b)(1)
MNI (Class II) - 888.3070(b)(1)
NKB (Class III) – 888.3070(b)(2)
Spinal Interlaminal Fixation Orthosis
KWP (Class II) – 888.3050

Common/Usual Name: Iliac Monoaxial Screws, Monoaxial Screws, Fixed locking caps, Rods, Hooks, Components, and Instruments

Device Trade Name: Malibu Spinal System

The devices used for comparison in this summary are Synthes Spine Company's Synthes Click'X Monoaxial Screw System (K031175), DePuy Acromed's Moss Miami Spinal System (K002607 and K992168) and SeaSpine Inc.'s UCR Spinal System (K993503, K021623, K031381, K032739/S1 and K043232).

1. **Intended Use:** (The statements of intended use are identical.)

The intended use of the Malibu Spinal System iliac monoaxial screws, monoaxial screws, fixed locking caps, rods, hooks, and components, is substantially equivalent to the intended use of the predicate devices. The intended use of the Malibu Spinal

System is as a temporary or permanent posterior, non-cervical implant to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.

The intended use of the **Malibu Spinal System,** when used as a **Pedicle Screw Spinal System or Spondylolisthesis Spinal Fixation Device System**, is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. The indications for use are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion (indication for use only when used as a Spondylolisthesis Spinal Fixation Device System),
- spondylolisthesis,
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis)
- spinal tumor,
- pseudoarthrosis, and/or
- failed previous fusion.

The intended use and indications of the **Malibu Spinal System,** when used as a **Spinal Interlaminal Fixation Orthosis or Hook Spinal System,** are limited to T1-L5 and are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- spondylolisthesis
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudarthosis, and/or
- failed previous fusion.

2. Description:

The Malibu Spinal System includes titanium alloy iliac monaxial and monaxial screws. Both screw types will be offered in numerous diameters and lengths. The screw is comprised of an integrated body and housing. Both screws are designed to

be part of the Malibu system, but are compatible with and work in conjunction with the components in the current UCR Spinal System. The product is supplied "NON-STERILE" and must be sterilized prior to use.

The Malibu Spinal System will also include titanium alloy caps, rods, and hooks. The caps will come in one size, the rods in two diameters, and the four types of hooks in a variety of sizes. All of these devices are designed to be a part of the stand alone Malibu Spinal System, but are compatible with and work in conjunction with the components in the current UCR Spinal System. The product is supplied "NON-STERILE" and must be sterilized prior to use.

The Malibu Spinal System will offer a wide variety of instruments that range from rod forks to hook pushers. These various instruments will be made primarily from various grades of stainless steel with a few components made from titanium alloy, Radel, and medical grade Pomalux. These items are supplied "NON-STERILE" and must be sterilized prior to use.

3. Technological Characteristics:

The iliac monoaxial screws, monoaxial screws, fixed locking caps, rods, hooks, components, and instruments in this notification are components of a new stand alone system called Malibu Spinal System, but are designed to be compatible with and work in conjunction with the components in the current SeaSpine UCR Spinal System. The devices in this submission have substantially equivalent technological characteristics to the predicate devices. Refer to **Table 1** in the following section, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, dimensional specifications, and material.

4. Comparison Analysis:

The overall designs of the Malibu Spinal System iliac monoaxial screws, monoaxial screws, fixed locking caps, rods, hooks, and components are substantially equivalent to the predicate devices. See **Table 1** on the following page for a comparison of the Malibu Spinal System iliac monoaxial screws, monoaxial screws, fixed locking caps, rods, hooks, and components to the predicate devices.

Malibu Spinal System

Feature	Malibu Spinal System	Synthes Click'X Monoaxial System	Moss Miami Spinal System	SeaSpine UCR Spinal System	Substantially Equivalent
Intended Use	The intended use of the Malibu Spinal System is as a temporary or permanent posterior, non-cervical implant to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.	Similar	Similar	Similar	Yes
Indications for Use	•Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, •spondylolisthesis, •trauma (*i.e.*, fracture or dislocation), •spinal stenosis, •deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis), •tumor, •pseudarthosis, and/or •failed previous fusion.	Similar	Similar	Similar	Yes
Design	Iliac monoaxial screws, monoaxial screws, fixed locking caps, rods, hooks, and components	Similar	Similar	Similar	Yes
Iliac Monoaxial Screws	See prints	Similar	Similar	Similar	Yes
Monoaxial Screws	See prints	Similar	Similar	Similar	Yes
Caps	See prints	Similar	Similar	Similar	Yes
Laminar Hooks	See prints	Similar	Similar	Similar	Yes
Pedicle Hooks	See prints	Similar	Similar	Similar	Yes
Offset Hooks	See prints	Similar	Similar	Similar	Yes
Material	Titanium alloy	Similar	Similar	Similar	Yes
Sterile	Non-sterile	Similar	Similar	Similar	Yes
Method of Sterilization	High-temperature steam	Similar	Similar	Similar	Yes
Mechanical Strength	See test results	Similar	Similar	Similar	Yes

Table 1: Summary of Design Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Ms. Diana Smith
Manager of Regulatory Affairs and Quality Assurance
SeaSpine, Inc.
2302 La Mirada Drive
Vista, California 92081-7862

Re: K051663
Trade/Device Name: Malibu Spinal System
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: III
Product Code: MNH, MNI, KWP, and NKB
Dated: June 15, 2005
Received: June 24, 2005

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051663

~~CONFIDENTIAL~~

Malibu Spinal System

Indications for Use Statement

510(k) Number (if known): K051663

Device Name: Malibu Spinal System

Indications for Use:

The intended use of the Malibu Spinal System, iliac monoaxial screws, monoaxial screws, fixed locking caps, rods, hooks, and components, is substantially equivalent to the intended use of the predicate device. The intended use of the Malibu Spinal System is as a temporary or permanent posterior, non-cervical implant to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.

The intended use of the **Malibu Spinal System,** when used as a **Pedicle Screw Spinal System or Spondylolisthesis Spinal Fixation Device System,** is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. The indications for use are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion (indication for use only when used as a Spondylolisthesis Spinal Fixation Device System),
- spondylolisthesis,
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis)
- spinal tumor,

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

(Division Sign-Off)
(Division Sign-Off) Office of Device Evaluation (ODE)
Division of General, Restorative, and Neurological Devices

510(k) Number K051663

Indications for Use Statement continued

- pseudoarthrosis, and/or
- failed previous fusion.

The intended use and indications of the **Malibu Spinal System,** when used as a **Spinal Interlaminal Fixation Orthosis or Hook Spinal System,** are limited to T1-L5 and are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- spondylolisthesis
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudarthosis, and/or
- failed previous fusion.

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of ~~CDRH,~~ Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051663